APR 2 9 2009

510(k) Summary for Dimension Vista® IGA Assay Dimension Vista® IGM Assay

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: 090594

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Siemens Healthcare Product GmbH
Emil von Behring Str. 76
Marburg, 35041 Germany

Contact Information: Siemens Healthcare Diagnostics
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: April 9, 2009

2. Device Name: Dimension Vista® IGA Flex® reagent cartridge
Dimension Vista® IGM Flex® reagent cartridge

Classification: Class II; Class II
Product Code: CFN
Panel: Immunology (82)

3. Identification of the Legally Marketed Device:

Siemens N Antisera to Human IgA (K042735)
Siemens N Antisera to Human IgM (K042735)

4. Device Description:

Dimension Vista® IGA Flex® reagent cartridge
Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a calibrator of known concentration.

Dimension Vista® IGM Flex® reagent cartridge
Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample.

The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

5. **Device Intended Use:**

Dimension Vista® IgA Flex® Reagent Cartridge:
The IgA method is an *in vitro* diagnostic test for the quantitative measurement of Immunoglobulin A in human serum and heparinized plasma by means of nephelometry on the Dimension Vista® System. Measurements of IgA aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Dimension Vista® IGM Flex® reagent cartridge:
The IgM method is an *in vitro* diagnostic test for the quantitative measurement of Immunoglobulin M in human serum and heparinized plasma by means of nephelometry on the Dimension Vista® System. Measurements of IgM aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

6. **Medical device to which equivalence is claimed and comparison information:**

The Dimension Vista® IGA reagent cartridge and Dimension Vista® IGM reagent cartridge and are substantially equivalent to the Siemens N Antisera to Human IgA assay (K042735) and Siemens N Antisera to Human IgM (K042735) respectively. The Dimension Vista® IGA and IGM assays, like the N Antisera to Human IgA and IgM assays are an *in vitro* diagnostic reagents for the quantitative measurement of Immunoglobulin A and Immunoglobulin M in human serum and plasma.

7. **Device Performance Characteristics:**

In support of the extended range, the Dimension Vista® IgA assay was compared to N Antiserum to Human IgA on the BN ProSpec® System by evaluating 28 serum samples at the extended low end of the assay range with concentrations ranging from 0.062 to 0.246 g/L. Regression analysis of these results yielded the following equations:

Method Comparison Study

	n	Slope (95%CI)	Intercept (95%CI)	Correlation Coefficient r	Correlation Coefficient r^2
Dimension Vista® IgA	28	1.000 (1.000, 1.000)	0.000 (0.000, 0.000)	0.992	0.983

In support extended range, the Dimension Vista® IgM assay was compared to N Antiserum to Human IgM on the BN ProSpec® System by evaluating 26 serum samples at the extended low end of the measuring range with concentrations ranging from 0.052 to 0.200 g/L. Regression analysis of these results yielded the following equations:

Method Comparison Study

	n	Slope (95%CI)	Intercept (95%CI)	Correlation Coefficient r	Correlation Coefficient r^2
Dimension Vista® IgM	26	1.023 (0.967, 1.122)	0.004 (-0.004, 0.008)	0.989	0.979

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics
c/o Ms Kathleen Ann Dray-Lyons
Manager, Regulatory Affairs
500 GBC Drive
P.O.Box 6101
Newark, DE 19714-6101

APR 29 2009

Re: k090594
Trade/Device Name: Dimension Vista® IGA Flex® reagent cartridge
Dimension Vista® IGM Flex® reagent cartridge
Regulation Number: 21 CFR §866.5510
Regulation Name: Immunoglobulins A, G, M, D and E Immunological Test System
Regulatory Class: Class II
Product Code: CFN
Dated: March 03, 2009
Received: March 05, 2009

Dear Ms Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090594

Device Name: Dimension Vista® IGM Flex® reagent cartridge

Indications For Use:

Dimension Vista® IGM Flex® reagent cartridge:

The IgM method is an *in vitro* diagnostic test for the quantitative measurement of Immunoglobulin M in human serum and heparinized plasma by means of nephelometry on the Dimension Vista® System. Measurements of IgM aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Prescription Use __X__ AND/OR Over-The-Counter-Use____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K090594

Indications for Use

510(k) Number (if known): K090594

Device Name: Dimension Vista® IGA Flex® reagent cartridge

Indications For Use:

Dimension Vista® IgA Flex® Reagent Cartridge:

The IgA method is an *in vitro* diagnostic test for the quantitative measurement of Immunoglobulin A in human serum and heparinized plasma by means of nephelometry on the Dimension Vista® System. Measurements of IgA aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Prescription Use ___X___ AND/OR Over-The-Counter-Use____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K090594